UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

FEDERAL TRADE COMMISSION and THE PEOPLE OF THE STATE OF NEW YORK, by LETITIA JAMES, Attorney General of the State of New York, Plaintiffs, v. QUINCY BIOSCIENCE HOLDING COMPANY, INC., a corporation; QUINCY BIOSCIENCE, LLC, a limited liability company; PREVAGEN, INC., a corporation d/b/a/ SUGAR RIVER SUPPLEMENTS; QUINCY BIOSCIENCE MANUFACTURING, LLC, a limited liability company; and MARK UNDERWOOD, individually and as an officer of QUINCY BIOSCIENCE HOLDING COMPANY, INC., QUINCY BIOSCIENCE, LLC, and PREVAGEN, INC., Defendants.	Case No. 1:17-cv-00124-LLS

DEFENDANTS' MOTION *IN LIMINE* TO PRECLUDE PLAINTIFFS OR THEIR EXPERTS FROM CHARACTERIZING THE MADISON MEMORY STUDY ANALYSES AS "POST HOC"

Pursuant to Federal Rule of Evidence 403, Defendants Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC, Prevagen, Inc., Quincy Bioscience Manufacturing, LLC (collectively, "Quincy") and Mark Underwood (together with Quincy, "Defendants") seek to preclude Plaintiffs the Federal Trade Commission (the "FTC") and the New York Attorney General (the "NYAG" and, together with the FTC, "Plaintiffs")[1] and their experts from introducing

[1] At the September 15, 2023 pre-trial conference, this Court indicated its view that the FTC should not be permitted to participate in the jury trial on the NYAG's claims, as the FTC is not entitled to

evidence, eliciting testimony, or otherwise characterizing or suggesting that any statistical analyses conducted by Quincy in connection with the Madison Memory Study are "post hoc" analyses because there is no evidence suggesting, much less demonstrating, that such analyses were "post hoc." In fact, the only affirmative evidence generated in discovery contradicts this claim and to suggest otherwise is likely to confuse and mislead the jury and unfairly prejudice Defendants.

In their Complaint, Plaintiffs allege that the Madison Memory Study's statistically significant results (specifically those in the relevant AD8 0-1 and AD8 0-2 study populations) were the result of "post hoc"[2] subgroup analyses conducted *after* Quincy "fail[ed] to find a treatment effect for the sample as a whole. (Dkt. 1 ¶ 29.) But extensive discovery in this case has not borne out this conclusory allegation. To the contrary, the record evidence plainly demonstrates that these analyses were planned from the beginning of the study. Mark Underwood, President of Quincy, testified that "Quincy decided to analyze certain groups of participants based on AD8 scores before the Madison Memory Study commenced." (Metzinger Decl.[3] Ex. 1, Dkt. 223 ¶ 28.) The Madison Memory Study's principal investigator, Kenneth Lerner, testified similarly. (Metzinger Decl. Ex. 2, Lerner Tr. at 125:23—126:2 (Q. When was the decision made to do analyses of the data on specific subgroups? A. I – I Believe that decision was made – that was the – that was the intention once we started the study.").)

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have a jury decide any of its claims. Defendants agree, and maintain that Mr. Underwood should not be a party to the jury trial as a result, but because this Court has not yet issued a final order on this point, bring this motion on behalf of Quincy and Mr. Underwood, with respect to both the FTC and the NYAG's claims.

[2] Plaintiffs insinuate that all "post hoc" analyses are inherently flawed; however, that is not the case.

[3] References to the "Metzinger Decl." are to the Declaration of Jaclyn M. Metzinger dated October 24, 2023 and filed herewith.

Plaintiffs have developed no evidence to contradict this testimony. Indeed, Plaintiffs' experts admitted that they did not actually know when the AD8 0-1 and AD8 0-2 analysis were planned or when these analyses were conducted. Dr. Mary Sano testified that she had not seen "any documents that give any information about when any alleged subgroup analysis was conducted." (Metzinger Decl. Ex. 3, Sano Tr. 182:11—184:13.) And Dr. Janet Wittes admitted that she did not know when the AD8 0-1 and AD8 0-2 analyses were planned or conducted. (Metzinger Decl. Ex. 4, Wittes Tr. 104:18—105:25.) In fact, Dr. Sano went so far as to admit that she *assumed* that the AD8 0-1 and AD8 0-2 analysis were conducted after the "total study population" was analyzed, but she could not point to any evidence supporting that assumption at her deposition. (Metzinger Decl. Ex. 3, Sano Tr. 182:11—185:25.)

In light of the record evidence, there can be no probative value to Plaintiffs' and their experts' unsupported characterization of the analyses as "post hoc." It is clear that Plaintiffs' use of the phrase "post hoc" in connection with the Madison Memory Study analyses is for pejorative purposes only and is not based on any record evidence.

Allowing Plaintiffs or their experts to suggest to the jury that these analyses are "post hoc" and, therefore somehow inherently flawed without any evidentiary basis (and with undisputed evidence to the contrary) is sure to mislead and confuse the jury and would be highly prejudicial to Defendants. *See Hart v. RCI Hosp. Holdings, Inc.*, 90 F. Supp. 3d 250, 257 (S.D.N.Y. 2015) ("Under Rule 403, the Court may exclude relevant evidence where its probative value is substantially outweighed by the risk of 'unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence.'"). Thus, any reference to "post hoc" analyses, "after the fact" analyses, or similar characterizations—whether in opening

statements, documentary evidence, expert testimony, closing argument or otherwise—should be precluded under Rule 403.

Respectfully submitted,

Dated: October 24, 2023

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